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Commentary

Parental consent for vaccination of minors against COVID-19

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1. Introduction

As of May 2021, emergency use authorization (EUA) for Pfizer's COVID-19 (COVID) vaccine applies to minors at least 12 years of age—some 25 million adolescents across the United States [1,2]. While this change marks a critical step towards herd immunity and return to normality in everyday life, it also raises a host of questions concerning parental consent for vaccination of minors in pandemic times, most notably: should parental consent be required for COVID vaccine administration?

2. Vaccination of minors: Legal background

Legislation on parental consent for vaccination varies significantly by both state and vaccine in question [3]. Texas, Colorado and Florida, for instance, require parental consent for all vaccines, while other states, like Washington, abide by "mature minor doctrines." Such doctrines permit minors deemed "mature enough" to understand the risks, benefits, and implications of their decisions to receive any care "within the mainstream of medical practice, not high risk, and provided in a nonnegligent manner" without explicit parental approval [3,4]. Still other states, including California, allow minors over 12 to receive only certain vaccines—namely, against HPV and Hepatitis B, both commonly sexually transmitted—without parent agreement [4].

Superimposed on these laws are two guiding principles. First, all states have statutes permitting minors to consent to medical care based on their legal status [3,5]. Minors who are married, emancipated, pregnant, or in the military, for instance, are generally considered in control of personal health-related decisions [3]. Second, broadly speaking, minors may typically seek and consent for services related to sexually-transmitted infections, pregnancy, family planning, and substance-related concerns without consent from parents, although specific laws vary by state [3]. When it comes to vaccines, this second principle is upheld incon-

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sistently, with some states—like California—abiding strictly, and others placing vaccination, even if against sexually transmitted infections, outside the statute's purview [4].

If, when, and where required, however, what does parental consent for health services, including vaccination, actually entail? Must all legal guardians sign on the dotted line, or is one sufficient? In practice, the process of consent for a minor's care is somewhat blurry and elusive, again varying by state, type of care, and the specifics of patient health and family circumstances [6]. Similarly, the consequences of disregarding consent laws—for patients, parents, providers—span the spectrum, but notably can include civil or even criminal offense charges against physicians [7].

3. Some considerations for vaccination against COVID without parental consent

What if a minor (specifically, age 12 or older) requests COVID vaccination against parental will or without parental knowledge? How ought the benefit this vaccination would offer—for the adolescent, their peers, their vulnerable or elderly contacts—be balanced with the risk of alienating parents and liability for the provider, whether or not vaccination resulted in some less-than-ideal outcome?

While there is no definitive, "one size fits all" moral answer to this question, key considerations for patients, parents, physicians—and, ultimately, policymakers—include the following, displayed in Table 1 [2–5].

The considerations listed in Table 1 are distinct from similar questions about other vaccines for a number of reasons. Most obviously, the risks and benefits, both individual and systemic, of COVID vaccination must be assessed in light of the magnitude, abruptness, and non-discriminatory global nature of the personal and public challenges COVID created (versus diseases prevented by other vaccines). Importantly, pediatric patients are hardly immune to the ravages of COVID; recent scholarship has found the "burden of disease" caused by COVID in children and adolescents "greater than that of many diseases for which vaccines are routinely recommended."[8]

Perhaps even more critically, however, the COVID vaccine is currently only available to minors (ages 12–15) under EUA [8,9]. Extant consent laws are designed for well-studied, FDA-approved vaccines—but the COVID vaccine is not (yet) that. Whether inciting hesitancy and concern—or a motivating sense of urgency and

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Table 1Key considerations, by category, in the assessment of parental consent for COVID vaccination of minors.

| Category | Minor-side considerations | Parent-side considerations |
|------------------------------|--|--|
| Patient age | On average, at what age are minors generally deemed "mature" by providers under existing mature minor doctrines? | On average, at what child age are parents willing to engage sons and daughters in discussion and debate about vaccination? |
| | How does this age compare to 12, the current minimum for COVID vaccination? | At what age(s) do concerned parents consider children "old enough" to receive the COVID vaccine? Why? |
| Motivation and benefits | Do minors want to be vaccinated? | How do parents situate the welfare of their own children within a broader social context? |
| | What are the primary reasons minors cite for desiring vaccination—personal protection, ability to return to school/activities, contribution to society and social responsibility? | What are some potential systemic consequences—both positive and negative—of minors' self-consent for schools, communities, and future vaccination efforts? |
| | | To what extent does systemic benefit of vaccination factor into parental decision making? |
| Concerns and risks | How do minors across ages conceive of the risks of COVID infection in themselves and their peers? | How do parents conceive of the risks of COVID infection in their children? |
| | In comparison, how do they conceive of the potential risks of vaccination? | Do they consider their children too "low risk" to risk vaccination? |
| | How do minors across ages understand Emergency Use | What about parents of children with chronic conditions? |
| | Authorization versus full FDA approval of vaccines? Should their understanding, or lack thereof, factor into consent decisions? Practically, do minors have access to their medical information/ records, or is access controlled by parents? And, if controlled by parents, how can minors reasonably be considered medically "emancipated" to consent for COVID vaccination? Will minors—or their providers—be required to inform parents of COVID vaccination status, regardless of whether parental consent was obtained to vaccinate? | In comparison, how do parents conceive of the potential risks of vaccination for their children? |
| | | Are parents hesitant about, or emphatically opposed to, vaccination of their children against COVID? |
| | | What are their attitudes towards other vaccines? |
| | | If hesitant and desiring additional information/assurance, when and given what data, would parents be willing to vaccinate their children? |
| | | How does Emergency Use Authorization (versus full FDA approval) factor into parental decision-making? |
| | | What are the most prevalent parental concerns around vaccination? |
| | | Short- versus long-term effects? |
| | | Effects on immunity versus future reproduction versus brain function? |
| | | Concern for future adverse events— malignancy, auto-immune conditions? |
| Information sources | From where are minors receiving vaccine-related information? | From where are parents receiving vaccine-related information? |
| | What roles do schools, pediatricians, peers and social media play in their decision making? | What roles do pediatricians play in parental opinion formation and decision making? |
| Other ethical considerations | How does the intensity and acuity of a pandemic backdrop influence the weight of minors', versus parents', desires and decisions? | How common is it that parents support vaccination of children other than their own? |
| | Are the risks of vaccination low enough, and benefits great enough, to make determination of "maturity" unnecessary—and simply permit vaccination of any willing minor of a certain age? | What are the primary justifications for their views? |
| | | How would COVID vaccination fold into existing patient-doctor confidentiality statutes? |
| | | Would vaccination without parental consent still be reported to guardians, or kept confidential? |
| | | What kinds of civil—or even criminal—issues or charges might the vaccine-providing pediatrician encounter? |
| | | What relevant protections are in place? |

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opportunity—the vaccine's EUA status cannot be ignored, and must factor into discussions about consent policy.

4. For policymakers

With these and other considerations in mind, policymakers must ultimately decide whether or not to allow modification of vaccination laws to permit, or even encourage, immunization of minors against COVID regardless of parental opinion or consent [8].

If they decide to allow it, they must consider how to do it. While potential approaches to such legal modification are numerous, most viable options fall into 3 broad categories:

- 1) **"Blind" allowance:** all minors over a predetermined age allowed to consent for their own COVID vaccine.
- Subjective allowance: expansion of mature minor doctrines to cover COVID vaccination, with or without an age floor [3,8].
- 3) **Alignment with privileged healthcare services:** categorization of COVID vaccination with care routinely allowed in absence of parental consent (e.g., sexual health) [3].

Whatever the approach taken, recent momentum towards maximally-widespread immunization is likely to continue, and individuals under 18 must now be factored into the flow of vaccination policy, process, and progress. Establishment of a safe yet conducive vaccination consent structure, in the setting of the standing state-specific legal landscape, is an urgent next step. While blind allowance is admittedly unlikely to receive endorsement, variations on subjective allowance or alignment with privileged services seem most prudent for minors and society alike.

5. For medical providers

Both subjective allowance and alignment with privileged service approaches align strongly with the primary goal of medical providers: to maximize their patients' protection—against COVID infection, damage to mental health from prolonged social isolation, exacerbation of underlying chronic disease, etc. [2].

Although official amendment of policy will likely be slow and contentious—as suggested by recent events across the country pitting providers against politics—providers should take steps now to ensure minors receive vaccination whenever possible and safe within the confines of existing legal constraints [9,10]. Using trusted resources to engage parents on the benefits and realistic risks of vaccination, for instance, may help assuage the fears of parents who come "from a place of caring," but are either mis- or under-informed about COVID immunization [2]. Providers may

even leverage this moment in time to reinforce the necessity and safety of vaccination in general.

As part of addressing parental concerns and optimizing patient wellbeing, providers should also weigh each minor's unique medical and social circumstances when deciding, now or under future amended policy, whether to vaccinate a child against COVID—with or without parental consent. Has a child received former vaccinations without issue, or does the patient have a condition—such as an immunodeficiency—limiting vaccination? A history of clinically-significant adverse reaction to vaccines? Does a child have a chronic illness, genetic or acquired, that dramatically increases the risk of serious COVID infection, making vaccination all the more important? How likely is a child to contract COVID in their environment? How likely are they, immune-wise, to respond to infection insufficiently? In addressing such questions, regardless of consent policy in place, providers can play a critical role in ensuring appropriately widespread vaccination.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- [1] Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic. FDA News Release. May 10, 2021. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use.
- Haelle T. Can teens get vaccinated if their parents object? National Geographic.
 May 25, 2021. https://www.nationalgeographic.com/science/article/canteens-get-vaccinated-if-their-parents-object.
- [3] English A, Shaw FE, McCauley MM, Fishbein DB. Legal basis of consent for health care and vaccination for adolescents. Pediatrics 2008;121(Suppl 1): S85-7. https://doi.org/10.1542/peds.2007-1115I.
- [4] Consent Laws by State. VaxTeen; 2020.
- [5] Wessel J. Can Minors Get the COVID-19 Vaccine Without Parental Consent? ACHI. May 6; 2021.
- [6] Moonay H. Vaccinations and Custody: What happens when divorced, separated or unmarried parents can't agree? JDSUPRA. April 19; 2021.
- [7] Informed Consent and Unauthorized Treatment. FindLaw, Medical Malpractice. Last updated November 30; 2018.
- [8] Morgan L, Schwartz JL, Sisti DA. COVID-19 Vaccination of Minors Without Parental Consent: Respecting Emerging Autonomy and Advancing Public Health Published online July 12. JAMA Pediatr 2021. https://doi.org/10.1001/jamapediatrics.2021.1855.
- [9] Jenco M. AAP: Don't use COVID-19 vaccine off-label for children. AAP News. August 23, 2021. https://www.aappublications.org/news/2021/08/23/fda-covid-vaccine-licensure-082321#:~:text=The%20FDA's%20licensure%20of%20the,to%2015%2Dyear%20age%20group.
- [10] Chappell B, Pfleger P. She Says She Was Fired For Saying That Teens Don't Need Parental Consent For Vaccines. NPR. July 13, 2021. https://www.npr. org/sections/coronavirus-live-updates/2021/07/13/1015742588/tennesseesousted-vaccination-chief-blasts-politics-over-teen-vaccines.